REMARKS

By this Amendment, claims 8, 38, 54, and 65 are canceled, without prejudice or disclaimer, claims 1, 30, 34, 47, 59, and 97-100 are amended, and claims 101 and 102 are added. Consequently, claims 1-7, 10-21, 23-37, 39-53, 56-64, and 66-102 are pending in this application, with claims 1, 34, 47, 59, 69, and 87 being independent. Of those pending claims, claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92, and 94-96 have been withdrawn from consideration as being allegedly drawn to non-elected species.

For the following reasons, Applicant respectfully requests reconsideration of this application and withdrawal of all of the rejections outstanding in the February 7, 2007 Office Action.

35 U.S.C. § 103(a) Rejection Based on Konomura and Levinson

Claims 1-4, 8, 10-18, 28-30, 31-40, 43-54, 56, 58-67, and 97-100 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura ("Konomura") in view of U.S. Patent No. 6,660,011 to Levinson ("Levinson"). For the following reasons, this rejection should be withdrawn.

In the rejection, the Examiner admits that Konomura does not disclose "a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue." (See Office Action at page 3.) Nonetheless, the Examiner asserts that "Levinson teaches of an analogous medical device used for tissue cutting and retrieval" and that "[i]t would have been obvious ... to have a tissue cutting end effector [of Levinson device] in the apparatus of Konomura to selectively capture, cut and/or

retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson."

Although Applicant does not necessarily agree with the Examiner's characterization of the claims and the teachings of Konomura and Levinson, Applicant has amended each of independent claims 1, 34, 47, and 59 to incorporate the subject matter of previous claims 97, 98, 99, and 100, respectively. Thus, each of independent claims 1, 34, 47, and 59, as amended, recites a "tissue cutting end effector [consisting] essentially of a snare loop."

Applicant notes that the Examiner also rejects the subject matter of previous claims 97-100. The Examiner asserts that "Levinson teaches of a set of wires 28 that act as a snare loop" and that "the tissue [cutting] end effector consists essentially of a snare loop, as the second set of wires 28 of Levinson is essential to the end effector 20 as seen in Figure 1." See Office Action at page 10. Applicant disagrees with this reasoning.

First, the Examiner's inquiry as to whether the second set of wires 28 is essential to the alleged "end effector" of Levinson is irrelevant in determining whether the alleged "end effector" of Levinson consists essentially of a snare loop. The language "consisting essentially of" is a term of art that limits the scope of a claim recitation to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed recitation. See, e.g., M.P.E.P. § 2111.03. Thus, the language "consisting essentially of" excludes any prior art device or method having additional materials or steps that materially affect the basic and novel characteristics of the recitation following the "consisting essentially of" language.

In this case, claims 1, 34, 47, and 59 each recite that "the tissue cutting end effector consists essentially of a snare loop." Thereby, any prior art "end effector" including any additional materials (i.e., additional to a snare loop) that materially affect the basic and novel characteristics of a "snare loop" should be excluded from consideration. As detailed below, the alleged "end effector" of Levinson includes at least one additional element that materially affects the basic and novel characteristics of a snare loop and, therefore, should be excluded for application against claims 1, 34, 47, and 59.

The alleged "end effector" of Levinson (which, according to the Examiner's proposed modification, replaces the basket forceps of Konomura) requires both the first set of wires 20 and the second set of wires 28 to enable capturing, cutting, and retrieving tissue. For example, after cutting tissue with the second set of wires 28, the first set of wires 20 forms a basket-like configuration with the second set of wires 28, as shown in Fig. 1, to capture and retrieve the cut tissue. See Fig. 9 and col. 5, lines 39-57. Thus, even though only the second set of wires 28 is used to cut tissue, the alleged "end effector" of Levinson additionally requires the first set of wires 20 for capturing and retrieving the cut tissue, which necessarily alters the basic and novel characteristics of a snare loop because a snare loop does not capture and retrieve cut tissue.

Since the alleged "end effector" of Levinson includes an additional element that materially affects the basic and novel characteristics of a snare loop, Levinson does not teach or suggests a "tissue cutting end effector [consisting] essentially of a snare loop." Therefore, independent claims 1, 34, 47, and 59, and their respective dependent claims, define novel and non-obvious subject matter over the cited references. Thus, Applicant

respectfully requests reconsideration and withdrawal of this 35 U.S.C. § 103(a) rejection.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and McAlister

Claims 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,599,324 to McAlister et al. ("McAlister").

Claims 5-7 depend, either directly or indirectly, from independent claim 1. As discussed above, independent claim 1 patentably distinguishes from the asserted combination of Konomura and Levinson. Also, McAlister does not supply the deficiencies of Konomura and Levinson. Therefore, claims 5-7 should also patentably distinguish from the cited references at least by virtue of their dependency from independent claim 1.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Okada

Claims 69-75, 81, 82, 89 and 93 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,871,440 to Okada ("Okada"). Applicant respectfully traverses this rejection.

Claims 69-75, 81, and 82

Independent claim 69 recites, among other things, "a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path ..., wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path."

In the rejection, the Examiner admits that Konomura and Levinson do not disclose the claimed flow path configuration. Nevertheless, relying on Fig. 30B of Okada, the Examiner alleges that Okada teaches a nozzle having the claimed flow path configuration and that "[i]t would have been obvious ... to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Okada and is well known in the art." Applicant disagrees with the Examiner's reasoning.

Konomura discloses a basket forceps assembly 1 comprising a hollow sheath 2 and a basket 3 that moves out of and into the front end of the sheath 2 for holding or fracturing a foreign matter. The basket 3 comprises a plurality of resilient wires 6 and a front end tip 7 to which the front ends of the wires 6 are secured. To solve the problem of inhibited or reduced fluid supply when the front end tip 7 is fitted into the front end of the sheath (e.g., col. 1, line 34 ~ col. 2, line 22), the front end tip 7 of Konomura is formed with one or more notched grooves 18, 18a, 18b or through openings 19a, 19b to provide fluid passages therethrough. These fluid passages enable continuous fluid supply when the distal tip 7 closes the front end of the sheath 2. See, e.g., col. 4, lines 14-51.

Different from Konomura device, Okada discloses an insertion section of an endoscope, which includes an observation lens and a washing nozzle for cleaning the observation lens. The embodiment shown in Fig. 30B (which the Examiner relies on to allege that Okada discloses the claimed flow path configuration) includes an observation lens unit 322 (see Figs. 29A and 29B) and a washing nozzle 372 for applying a washing solution onto the front surface of the observation lens unit 322.

Although the specification of Okada is completely silent as to the specific configuration of the washing nozzle 372, the Examiner appears to be relying on the shape of the washing nozzle 372 shown in Fig. 30B.

Even assuming, for the sake of argument, that the washing nozzle 372 of Okada indeed discloses the claimed flow path configuration, one of ordinary skill in the art would not have combined the alleged teachings of Konomura and Okada because there would not have been any particular reason to do so.

For example, as discussed above, the purpose of the fluid passages in the distal tip 7 of Konomura is to continuously supply fluid when the front end of the sheath 2 is closed with the distal tip 7. Thus, these fluid passages need only to allow a desired amount of fluid to be fed therethrough. There is nothing in Konomura that suggests "greater control over the outputted flow of fluid" (i.e., alleged by the Examiner as the motivation to modify the fluid passages of Konomura) is required or even desired. Nor is there any indication that such a feature would have improved the functionality or operability of Konomura. Consequently, even if the alleged teaching of Okada were available to one skilled in the art, he or she would not have modified the fluid passages of Konomura to employ the washing nozzle 372 of Okada because there would not have been any particular reason to do so.

Moreover, contrary to the Examiner's allegation, the washing nozzle 372 of Okada does not appear to teach "greater control over the outputted flow of fluid" than the flow passages of Konomura. Nor has the Examiner provided any factual basis to support his allegation that such is "well known in the art." The washing nozzle 372 of Okada is for cleaning the observation lens unit 322 located adjacent the nozzle 372,

and nothing in Okada teaches or even suggests that its washing nozzle 372 provides "greater control over the outputted flow of fluid." Also, it is highly unlikely that one of ordinary skill in the art considering Okada would have found that its nozzle 372 taught or suggested the teaching alleged by the Examiner.

The Examiner's asserted combination of the cited references clearly reflects impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, the asserted combination of Konomura and Okada would not have been suggested since there is no reason to make the Examiner's proposed combination or modification.

For the reasons set forth above, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been properly established. Thus, independent claim 69 and its dependent claims patentably distinguish from the cited references.

Claims 89 and 93

Claims 89 and 93 depend from independent claims 47 and 59, respectively. As discussed above, independent claims 47 and 59 patentably distinguish from the asserted combination of Konomura and Levinson, and Okada does not supply the deficiency of Konomura and Levinson. Thus, claims 89 and 93 should also patentably distinguish from the cited references at least by virtue of their respective dependency from independent claims 47 and 59.

For the reasons set forth above, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Termanini

Claims 87 and 88 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 4,204,528 to Termanini ("Termanini"). Applicant respectfully traverses this rejection.

Independent claim 87 recites, among other things, "a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path ..., wherein the flow path comprises an inlet and a plurality of outlets connecting to the inlet."

In the rejection, the Examiner admits that Konomura and Levinson do not disclose the flow path having "an inlet and a plurality of outlets connecting to the inlet." Nevertheless, the Examiner alleges that Termanini teaches "an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7)" and that "[i]t would have been obvious ... to vary the outlet area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Termanini and is well known in the art." Applicant disagrees with the Examiner's reasoning.

Termanini discloses a device that is distinctly different from the devices of Konomura and Levinson. While Konomura and Levinson disclose surgical devices (i.e., a basket forceps of Konomura and a tissue cutting and retrieving device of Levinson), Termanini discloses a fiber-optic catheter 12 for visual inspection of the cardiovascular system. The catheter 12 includes bundles 14, 18 of light-conducting fibers enclosed within a flexible sheath 22. At the center of the sheath 22 is a lumen 24, and a flexible tubing 30 is slidably disposed within the lumen 24. The tubing 30 carries a saline

solution from the proximal end of the catheter 12 to the distal end thereof. The distal end of the tubing 30 includes a spray head 30 with a plurality of apertures 40. Dispersing the liquid solution into the bloodstream through the apertures 40 displaces the blood medium with the clear saline solution, thus permitting improved viewing of the vessels and organs within the cardiovascular system. See, e.g., col. 1, lines 51-57, and col. 4, lines 33-50, of Termanini. Since the injection is synchronized with the pulsation of blood from the heart, which requires displacement of blood in a relatively short time period, the spray head 36 with a plurality of apertures 40 appears to enhance the blood displacement. As will be explained below, however, one of ordinary skill in the art would not have combined the alleged teachings of the references in the manner proposed by the Examiner.

First, as discussed above, the purpose of the fluid passages in the distal tip 7 of Konomura is to continuously supply fluid when the front end of the sheath 2 is closed with the distal tip 7. Thus, these fluid passages need only allow a desired amount of fluid to be fed therethrough. Also, nothing in Konomura suggests the need for spraying the fluid or "greater control over the outputted flow of fluid," as alleged by the Examiner. Therefore, even if the alleged teaching of Termanini were available to one skilled in the art, he or she would not have modified the fluid passages of Konomura to employ the spray head 36 of Termanini because there would not have been any reason to do so.

Moreover, modifying the distal tip 7 of Konomura to have a plurality of apertures, as allegedly taught by Termanini, would not serve any purpose other than complicating the design of the distal tip 7 of Konomura, thereby increasing the manufacturing costs.

Such adverse effects would have sufficiently deterred one of ordinary skill in the art from modifying the distal tip 7 of Konomura to have the spray head 36 of Termanini.

Further, contrary to the Examiner's allegation, the spray head 36 of Termanini does not appear to teach or otherwise suggest "greater control over the outputted flow of fluid" than the flow passages of Konomura. Nor has the Examiner provided any factual basis to support his allegation that such is "well known in the art." The spray head 36 is to inject saline solution into the bloodstream to displace blood medium around the head 36, permitting improved viewing of the vessels and organs within the cardiovascular system. As is apparent, nothing in Termanini teaches or suggests that its spray head 36 provides "greater control over the outputted flow of fluid." It is even more doubtful that one of ordinary skill in the art would have considered the spray head 36 of Termanini as having taught the alleged "greater control over the outputted flow of fluid."

Again, the Examiner's asserted combination of the cited references reflects impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, the asserted combination of Konomura and Termanini would not have been suggested since there is no reason to make the Examiner's proposed combination or modification.

For the reasons set forth above, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been properly established. Thus, independent claims 87 and dependent claim 88 patentably distinguish from the cited references. Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

Conclusion

Applicant respectfully requests reconsideration of this application, withdrawal of all of the outstanding rejections, and allowance of all pending claims.

The Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicant declines to necessarily subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Should the Examiner wish to discuss this case, he is invited to call the undersigned at 202-408-4140.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: June 22, 2007

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